DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M3768N

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

MAY 1 9 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WL-52-00
Inspection ID: 1900250003

Gary Levine
West Coast Radiology Center
999 North Tustin Street #209
Santa Ana, CA 92705

Dear Mr. Levine:

We are writing to you because on 4/25/2000, your facility was inspected by a representative of the State of California, on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 finding at your facility:

- **Phantom QC records were missing for 5 weeks for unit 1, General Electric Co. (GE Medical Systems), 600T, room GE 109.**

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

In addition, your response should address the Level-2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level-2 findings are:

1. **Corrective actions for processor QC failures were not documented at least once for processor 2, Kodak, RP X-OMAT M6B, 6AN, 6AW, room Downstairs at site West Coast Radiology Center.**

2. **Mammograms were processed in processor 2, Kodak, RP X-OMAT M6B, 6AN, 6AW, room Downstairs at site West Coast Radiology Center, when it was out of limits on 3 days.**

3. **Processor QC records were missing 2 consecutive days for processor 2, Kodak, RP X-OMAT M6B, 6AN, 6AW, room Downstairs at site West Coast Radiology Center.**

4. **Processor QC records were missing 4 out of 20 days of operation in month 01/2000. Processor QC records missing 20%, for processor 2, Kodak, RP X-OMAT M6B, 6AN, 6AW, room Downstairs at site West Coast Radiology Center.**

5. **Corrective action for a failing image score (before further exams) was not documented for unit 1, General Electric Co. (GE Medical Systems), 600T, room GE 109.**

6. **Corrective action for a failing image score (before further exams) was not documented for unit 3, General Electric Co. (GE Medical Systems), 600T, room GE 209.**

7. **Corrective action for a failing image score (before further exams) was not documented for unit 4, Lorad Medical Systems Inc., MIII, room Lorad.**

8. **The interpreting physician did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36 month period:** [redacted]

9. **5 of 10 random reports reviewed did not contain an assessment category for site West Coast Radiology Center.**

10. **There was no examples or nor attempts to get biopsy results for site West Coast Radiology Center.**

It is necessary for you to act on this matter immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter.

- The specific steps you have taken to correct all of the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.
- Equipment settings (including technique factors), raw test data, and calculated final results, where appropriate, and sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records **(Note: Patient names or identification should be deleted from any copies submitted).***

*This note is not applicable for letters which also address patient notification.

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/dmqrp.html <http://www.fda.gov/cdrh/dmqrp.html>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas at (949) 798-7708 or Minh Phan at (949) 798-7711.

Sincerely yours,

Mark Roh
Acting District Director

cc: County of Los Angeles
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